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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,398	07/23/2007	Ansui Xu	20458-004US1 CGL04/0118US	2694
26191 7590 03/17/2010 FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER GWARTNEY, ELIZABETH A	
			ART UNIT	PAPER NUMBER
			1794	
			NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/593,398	Applicant(s) XU ET AL.	
	Examiner Elizabeth Gwartney	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/25/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8 and 21-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8 and 21-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Amendment filed November 25, 2009 has been entered. Claims 21-30 have been added and claims 2, 3 and 9-20 have been cancelled. Claims 1, 4-8 and 21-30 are pending.
2. The previous 112 2nd Paragraph rejections have been withdrawn in light of applicant's amendments made November 25, 2009.
3. The provision double patenting rejection under 35 U.S.C. 101 has been withdrawn in light of applicants amendment made November 25, 2009 and provided co-pending US Application No. 11/084,197 has been abandoned.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 4-8 and 21-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites “about 5-15% vital wheat gluten or wheat protein isolate”. While there is support in the specification for to include 0-30% , 5-20% ([13]), 5% or 8% ([33]/Examples 10-16), there is no support to include about 5-15% vital wheat gluten or wheat protein isolate with the composition as limited in amended claim 1.

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Claim 1 recites “wherein said formulation results in a food product having about 20-40% fat, about 30-45% effective carbohydrates and about 10-25% total dietary fiber.” While there is support in the specification for food products having fat, effective carbohydrates and total dietary fiber in the specific quantities provided in Examples 1-9 of paragraph 28 and Examples 10-16 of paragraph 16 and ranges provided for in paragraphs 11-12, there is no support for the specific ranges as limited in amended claim 1.

Claim 30 recites “[a] food formulation comprising: a) about 50% fine masa corn flour; b) about 20% cooked and ground corn bran; c) about 5% of pre-gelatinized corn flour; d) about 20% ground corn germ; and e) about 5% corn gluten meal.” While there is support for a composition comprising the precise percentages recited in claim 1, there is not support for the more broad limitation “about.”

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
9. Claim 1, 4-8 and 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiang et al. (US 6,491,959) in view of Wu et al. ("Analysis of Headspace Volatiles of Corn Gluten Meal" in Cereal Chemistry-2003), Dohl et al. (US 2005/0013900), Delrue et al. (US 6,383,547), and Knehr ("Going With the Grain" in Food Product Design-1998).

Regarding claims 1, 5-7, 22-24, 26 and 30, Chiang et al. disclose a corn-based snack composition comprising about 30% by weight to about 80% by weight limed yellow corn flour such as Maseca corn flour (C11/L61-C12/L8), from about 0.5% by weight to about 10% by weight toasted corn germ (C9/L38-40), about 5% by weight to about 25% by weight pregelatinized waxy starch (C6/L9-11), about 5% by weight to about 20% by weight pregelatinized corn flour (C9/L12-14) and about less than 20% by weight fat. Chiang et al. disclose that the particle size distribution of the Maseca corn flour may be less than or equal to about 20% by weight retained on a 60 U.S. mesh screen and at least 40% by weight retained on a 120 U.S. mesh screen (C11/L66-C12/L3). Chiang et al. disclose that toasted corn germ is included to enhance the natural corn flavor of the snack product and provide the snack product

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with a pleasant roasted nut or pop-corn flavor (C9/L28-33). Further, Chiang et al. disclose a corn-based snack having the taste of a corn chip or a corn tortilla chip (Abstract, C6/L45-49).

Given Chiang et al. disclose a corn tortilla chip since change in size and shape does not make a particular product patently distinct over the prior art absent persuasive evidence that the particular configuration of the claimed invention is significant (MPEP 2144.04[R-1]), it would have been obvious to one of ordinary skill in the art at the time of the invention to have made the corn tortilla chip of Chiang et al. in any size and shape including that of a taco shell.

Regarding the method limitations recited in claims 22-24 (i.e. baked or baked and fried), it is noted that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated in Thorpe, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. In re Pilkington, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.).

While Chiang et al. disclose a corn-based snack composition comprising toasted corn germ up to a level of about 10%, the reference does not explicitly disclose 15-27% or about 20% corn germ. As corn flavor intensity is a variable that can be modified, among others, by adjusting the amount of corn germ additive, the precise amount would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed amount of corn germ cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would

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have optimized, by routine experimentation, the amount of corn germ in the corn-based snack composition of Chiang et al. to obtain the desired corn flavor intensity (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

While Chiang et al. disclose a corn-based snack food composition, the reference does not disclose that the composition comprises about 5-10% corn gluten meal, about 5-15% vital wheat gluten or wheat protein isolate, or about 115-41% ground corn bran.

Wu et al. teach that corn gluten meal is a high-protein fraction remaining in the corn wet-milling process (p. 597/Introduction). Wu et al. teach that because corn gluten meal is high in protein and specifically in cystine and methionine it is a good complement for other plant proteins efficient in these amino acids and could be used in combination with other plant proteins to make complete proteins for human nutrition (p. 597/Introduction). Wu et al. teach that the taste of corn gluten meal is acceptable when added as 5-10% of a food product (p. 567/Introduction).

Chiang et al. and Wu et al. are combinable because they are concerned with the same field of endeavor, corn fractions used in food compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included 5-10% corn gluten meal in the corn-based snack food composition of Chiang et al. for the purpose of increasing the protein content and nutritional status of the final corn-based snack product.

Dohl et al. teach a high-protein, low-carbohydrate baked products comprising wheat protein isolate in an amount of about 1.5% by weight to 40% by weight (*see* [0039]/Table 1

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wherein the preferred range of wheat protein isolate is 5-50% baker's percent). Dohl et al. teach wheat protein isolate comprises at least about 85% by weight protein ([0018]).

Chiang et al. and Dohl et al are combinable because they are concerned with the same field of endeavor, namely, baked food products. Since wheat protein isolate is at least about 85% protein and is known to be used in baked food products, it would have been obvious to one of ordinary skill in the art to have included wheat protein isolate in the corn-based snack food composition of Chiang et al. to increase protein content.

Delrue et al. teach adding a cooked corn bran additive at a level of at least about 0.5% by weight to enhance the strength and stability of tortillas and related food products made from corn masa (Abstract, C2/L41-C3/L12, C4/L39-515, Figure 1, C7-C9/2.Method for Preparing the Additive Composition). Delrue et al. teach that the corn bran additive is added to masa flour at a level of at least about 0.5%.

Knehr teaches that corn bran contains 86-90% total dietary fiber and can be used in high-fiber food products (p.2/An Earful). Knehr teaches that corn fiber helps strengthen the final product (p.2/An Earful).

Chiang et al., Delrue et al. and Knehr are combinable because they are concerned with the same field of endeavor, namely, corn -based food compositions. It would have been obvious to one of ordinary skill in the art to have included at least about 0.5% by weight of a cooked corn bran additive, as taught by Delrue et al., to the corn-based snack composition of Chiang et al. for the purpose of improving the strength and stability and increasing the total dietary fiber content of the corn-based food product produced.

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Given modified Chiang et al. disclose a corn-based snack food composition substantially similar to that presently claimed, intrinsically the composition would result in a snack food product having about 20-40% fat, 30-45% effective carbohydrates and about 10-25% total dietary fiber.

Regarding claims 4, 8, 21 and 25, modified Chiang et al. disclose all of the claim limitations as set forth above. While Chiang et al. disclose a corn-based snack food product, the reference does not explicitly disclose tortillas or breakfast cereal. Since Delrue et al. teach that it was known to make tortillas with a corn-based composition (C11/L31-C12/L32) and since some breakfast cereals are known to be corn-based, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the composition of modified Chiang et al. to make any corn-based snack food composition, including breakfast cereal and tortillas.

Regarding the method limitations recited in claims 21 and 25 (i.e. baked), it is noted that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated in Thorpe, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. In re Pilkington, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.).

Regarding claims 27-29, modified Chiang et al. disclose all of the claim limitations as set forth above, however, the references do not explicitly teach the granulation size of the ground corn bran, pre-gelatinized flour or ground corn germ ingredients. While perceived smoothness

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of the final corn-based snack product is a variable that can be modified, among others, by varying the granulation size of ingredients, the precise granulation size of the ground corn bran, pre-gelatinized flour and ground corn germ would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed granulation size of the ground corn bran, pre-gelatinized flour and ground corn germ ingredients cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the granulation size of the ground corn bran, pre-gelatinized flour and ground corn germ in the composition of modified Chiang et al. to obtain the desired final product texture (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Response to Arguments

9. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Friday; 7:30AM - 3:30PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./

Examiner, Art Unit 1794

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1794